



DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

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Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

NWE-02-99W

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 23, 1998

Mr. Mark W. Gordon, President
Bostonian Fishery, Inc.
695 Park Avenue
Bloomfield, CT 06002

Dear Mr. Gordon:

On September 24, 28, 1998, the Food and Drug Administration (FDA) conducted an inspection of your plant located at 695 Park Avenue, Bloomfield, Connecticut. The investigator documented violations of Section 402 (a)(4) of the Federal Food Drug and Cosmetic Act and Title 21, Code of Federal Regulations (21CFR) Parts 110 "Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food" (GMPs) and 123 "Safe and Sanitary Processing and Importing of Fish and Fishery Products" (Seafood HACCP Regulation), as follows:

- Monitoring records of temperature or cooling media of scombrotoxic species at receiving, holding, are not always prepared (21 CFR 123.6 (c)(7)).
- There is no monitoring of plant sanitation in accordance with 21 CFR 123.11(b) nor maintenance of sanitation control records as required by 21 CFR 123.11(c).

The above identified deviations are not intended to be an all inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations.

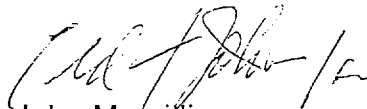
FDA will not issue any certificates for export of any of the seafood products processed

at your facility until your firm is fully in compliance with the seafood HACCP regulations. You should take prompt action to correct these deviations. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure and/or injunction.

You should notify this office in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. If corrective action cannot be completed within fifteen (15) working days, state the reason for the delay and the time within which corrections will be completed.

You may direct your reply to E. Frank Gesing, Compliance Officer, at the address noted above. If you have any questions concerning this matter, please contact Mr. Gesing at (781) 279-1675, Extension 127.

Sincerely,

A handwritten signature in dark ink, appearing to read "John Marzilli", with a stylized flourish at the end.

John Marzilli

District Director

New England District Office

cc: Andrew S. Gordon
Vice President
Bostonian Fishery, Inc.
695 Park Avenue
Bloomfield, CT 06002